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1.0 Fluorescent Lamp Study Quality Assurance Project Plan

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Preparation Date (Day/Month/Year): 3/20/01	
Investigative Organization's Project Manager: John James, ME DEP	
	Signature/Date
Investigative Organization's Project QA Manager: Deb Stahler, ME DEP	
Approval Signature: Jeri Weiss, USEPA NE	Signature/Date
Approval Signature: Pat Svetaka, USEPA NE	Signature/Date
	Signature/Date
Document Control Number:	

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2.0 Table of Contents/ Introduction/ Document Control

2.1 Introduction: The bureau proposes to arrange for laboratory analyses to determine the mercury content of 4-foot fluorescent lamps that are TCLP compliant and of those that are not. "TCLP-compliant" means a lamp that is determined to be non-hazardous using the Toxic Characteristic Leaching Procedure (TCLP). Laboratory analyses will be conducted on a statistically valid sample of T8 (1" diameter) and T12 (1½" diameter) lamps from each of three U.S manufacturers-Philips Lighting Company, Osram Sylvania, and GE. TCLP and total mercury analyses will be conducted on each lamp.

The analyses called for under this work plan will provide data bearing on whether Maine should retain its ban on disposal of all mercury added fluorescent lamps in solid waste. The data will improve knowledge of mercury levels in lamps, thereby enabling policymakers to take informed and better targeted actions to reduce mercury emissions. For example, by these independent analyses, the department seeks better information regarding the potential emissions should these lamps be disposed in ways that facilitate the release of mercury. In addition, the analyses are expected to yield accurate and reliable data bearing on the relevance and efficacy of the TCLP for measuring the environmental impacts of lamp disposal.

2.2 **Document control:**

2.2.1 Each page of the QAPP will contain the header:

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- 2.2.2 Each revision will be differentiated with a new revision number and date.
- 2.2.3 Controlled copies of the QAPP will be assigned a document control number. Document control numbers are listed on EPA-NE QAPP Worksheet #3.
- 2.3 Revisions: This document has been revised based on stakeholder comments. Comments received are included in Appendix H.

The following worksheets are included in Appendix A:

Worksheet 2

EPA-NE QAPP Worksheet

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3.0 Distribution List and Project Personnel Sign off Sheet:

- 3.1 Controlled copies of the QAPP will be distributed according to the distribution list in EPA-NE QAPP Worksheet #3. Each person receiving a controlled copy will also receive any updates/ revisions. If uncontrolled copies are distributed, it will be the responsibility of the person distributing the uncontrolled copy to provide updates/ revisions.
- 3.2 Personnel actively engaged in sample collection, data analysis and data validation for this project are required to read applicable sections of this QAPP and sign the Personnel Sign-Off Sheet.

The following worksheets are included in Appendix A:

Worksheet 3 Distribution list

Worksheet 4 Project Personnel Sign off Sheet

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4.0 **Project Organization:** The Maine Department of Environmental Protection [MEDEP] is responsible for coordinating all aspects of this project. The QAPP and any revisions to the QAPP will be written/documented by MEDEP. The sampling plan SOP will be written by MEDEP, and new lamps will be purchased and sent to the laboratory by MEDEP. MEDEP will package and ship used lamps that will be provided by Northeast Lamp Recycling facility. Fixed laboratory analytical work will be performed by Hampton-Clarke, Inc./ Veritech Laboratories. Laboratory data will be validated according to EPA Region 1 Functional Guidelines by Kestrel Environmental Technologies or Althea Lindell. Data usability will be assessed by MEDEP.

The following EPA-NE QAPP Worksheets are included in Appendix A:

4.1	Worksheet 5a	Project Organizational Chart
4.2	Worksheet 5b	Communication Pathways
4.3	Worksheet 6	Personnel Responsibilities and Qualifications

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5.0 Project Planning/ Project Definition:

5.1 Project Planning Meetings: Four project planning meetings were held to determine the scope of this project. These meetings are documented on Worksheet 8a in Appendix A. Individuals attending these meetings, and their role in the project are listed below. In addition to these individuals, input was solicited by phone from Veritech Laboratory manager Stan Gillowicz and the data validator Althea Lindell.

David Lennett	Bureau Director, Project Sponsor
Stacy Ladner	Writer, Universal Waste Rules
John James	Project Manager
Jim Hynson	Grant Writer
Deb Stahler	Project QA Officer
Enid Mitnik	Sampling Collection

5.2 Project Definition/ Background information:

In its 1997 annual report, Maine's Land & Water Resources Council recommended action to reduce mercury emissions by diverting mercury-added products from the solid waste stream. The Council subsequently prepared a report that identified specific mercury-added products and recommended a ban on their disposal in solid waste.

The Maine Legislature recently enacted the recommended disposal ban following extensive debate on whether the ban should apply to all fluorescent and other mercury-added lamps. Debate focused on whether the ban should apply to lamps that pass the TCLP. Under current state and federal hazardous waste laws, TCLP-compliant lamps can be placed in the solid waste stream. Non-compliant lamps, except those from households, must be recycled or sent to a hazardous waste disposal facility.

At issue in the Legislative debate was whether the cost of diverting TCLP-compliant lamps from the waste stream and recycling the lampsis warranted. The Legislature opted to prohibit disposal of all mercury-added lamps. However, the ban may be reconsidered in 2002 at which time the department is required to provide an assessment of the economic and environmental impacts of the ban as applied to TCLP-compliant lamps. To conduct this assessment, empirical data currently lacking in the public domain is needed regarding the actual mercury content of lamps represented as TCLP-compliant. The mercury content of these lamps is a matter of debate in light of information suggesting that manufacturers may achieve TCLP compliance in part by adding components to the lamp that impair the effectiveness of the testing procedure.

The analyses called for under this work plan will provide data bearing on whether Maine should retain its ban on disposal of TCLP compliant lamps in solid waste.

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The data will improve knowledge of mercury levels in lamps, thereby enabling policymakers to take informed and better targeted actions to reduce mercury emissions. For example, through these independent analyses, the department seeks better information regarding the potential emissions should these lamps be disposed in ways that facilitate the release of mercury. In addition, the analyses are expected to yield accurate and reliable data bearing on the relevance and efficacy of the TCLP for measuring the environmental impacts of lamp disposal.

The following EPA-NE QAPP Worksheets are included in Appendix A:
Worksheet 8a Project Scoping Meeting Attendance Sheet/ Agenda
Worksheet 8b Problem Definition/ Site History and Background

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6. Project Description and Schedule

6.1. Project Overview: This project proposes to quantify mercury amounts in fluorescent lamps so that policy makers can make more informed decisions about how to manage spent lamps. The results will be used to ascertain the mercury content of lamps represented as TCLP-compliant and those that are not. "TCLP-compliant" means a lamp that is determined to be non-hazardous using the Toxic Characteristic Leaching Procedure (TCLP).

Laboratory analyses will be conducted on a statistically valid sample of T8 (1" diameter) and T12 (1½" diameter) lamps from each of three U.S manufacturers--Philips Lighting Company, Osram Sylvania, and GE. TCLP and total mercury analyses will be conducted on each lamp.

- Sampling Tasks: Four foot fluorescent lamps representing four different production batch numbers for each of 10 lamp models representative of the most popular models of the three primary lamp manufacturers will need to be purchased, labeled, packed, and shipped to the analytical laboratory. In addition, used fluorescent lamps for each of the 10 lamp models targetted for this study will be provided by Northeast Lamp Recycling. ME DEP will provide the analytical laboratory with a list of samples to be analyzed for the first round of testing. Preliminary results from this first round will be reviewed by the laboratory to assess QC criteria as listed in worksheets 21 and 24a, and evaluated for sample representativeness [ME DEP] prior to further testing. In addition the laboratory data package will be evaluated for completeness by the data validator prior to accepting further data packages.
- Analytical Tasks: Fluorescent lamps will be tested on a "whole lamp" basis for TCLP mercury and total mercury. Since the traditional TCLP method has been shown to give inconsistent results, our TCLP extraction method is based on the 1992 SAIC study and protocols for sample preparation provided by NEMA. "Whole lamp" total mercury analyses will also be performed to avoid the inconsistency of results. Hampton-Clark, Inc/ Veritech Laboratories in Fairfield, NJ has been selected to perform these tests because they have the specialized equipment needed to perform "whole lamp" analyses and due to their experience with these analyses.
- Data Verification and Validation Tasks: All final data will be validated by an independent data validator according to tier III procedures outlined in Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses.
- Quality Assurance Assessments: The sampling process will be evaluated prior to sending samples to the laboratory. The laboratory will complete performance evaluation samples for both TCLP mercury and total mercury prior to analyzing samples. The laboratory has an internal audit system, and the most recent internal audit report has been forwarded to ME DEP for evaluation. The Army Corps of Engineers has audited the laboratory as well, and the latest audit report has been forwarded to ME DEP for evaluation. No further laboratory assessment is planned.
- Data Usability Assessments: All validated data will be evaluated and reconciled with project quality objectives by the project QA manager.
- Records and Reports: For sampling, a record of lamp models and batch numbers will be kept with chain of custody sheets. Laboratory data will include a data package for

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each batch of 20 samples to support Tier III data validation. Reports include data validation, QA, and final project report. These records are listed in Appendix A worksheet 26.

6.2. Project Schedule: Appendix A worksheet 10 outlines the project schedule. A driving force for this schedule is a report to the legislature in support of recent legislation. The report is due in January, 2002; thus there is some limited flexibility in the proposed schedule.

The following EPA-NE QAPP Worksheets are included in Appendix A:

Worksheet 9a Project Description

Worksheet 9b Contaminants of Concern/ Target Analytes Table
Worksheet 9c Field and Quality Control Sample Summary Table

Worksheet 9d Analytical Services Table

Worksheet 10 Project Schedule Timeline Table

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- 7. Project Quality Objectives and Measurement Performance Criteria
 - 7.1. Project Quality Objectives: Data from this study will help to determine the Department's rules governing disposal of fluorescent lamps, a universal waste. Two tests are being performed. For the TCLP mercury test, the TCLP pass/ fail status of the different lamp models is being confirmed. Data must be of sufficient quality to support hazardous waste characterization according to US EPA Test Methods for Evaluating Solid Waste, Chapter 9. For total mercury tests data should identify the total mercury mean ±10% for each lamp model within a 95% confidence level.
 - 7.2. Measurement Performance Criteria are specified on Worksheet11b, 24a.
 - Precision:
 - Analytical precision for total mercury will be assessed using laboratory control sample duplicate RPD calculations.
 - Analytical precision for TCLP mercury will be assessed using matrix spike duplicate RPD calculations.
 - Accuracy/ Bias
 - Blank contamination may not exceed method quantitation limits or 5% of the sample result.
 - Laboratory accuracy for total mercury will be monitored with laboratory control sample % recovery calculations.
 - Laboratory accuracy for TCLP mercury will be monitored with matrix spike % recovery calculations
 - One PE Sample for TCLP mercury and one for total mercury will be submitted by ME DEP and analyzed to assess laboratory performance/ accuracy as a prequalification check to ensure the laboratory is ready to analyze project samples.
 - Representativeness is optimized by analyzing four separate production batch dates for each lamp model, and up to five replicates of lamps in each production batch. Used lamps for each lamp model obtained from a lamp recycling facility will also be tested. Statistical tests will be used to assess the variance within each lamp classification and each lamp model.
 - Completeness: 100% completeness is the goal of this project, and will be assessed using the statistical tools mentioned in 7.1. If the variance of results is such that 20 samples for each lamp model is not sufficient, then limitations on the data may apply and the confidence level of existing data will be calculated and specified in the final project report. Every effort will be made to assure 100% completeness.
 - Comparability: Comparability will be ensured by strict adherence to standard operating procedures.
 - Sensitivity: Quantitation limits for these tests are given in worksheet 9b. Laboratory detection limits are at least ten times lower than the project quantitation limits. Project quantitation limits are four to ten times lower than associated level of concern.

The following EPA-NE QAPP Worksheets are included in Appendix A:

Worksheet 11a Project Quality Objectives/ Decision Statements

Worksheet 11b Measurement Performance Criteria Table

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8. Sampling Process Design

Sampling Design Rationale: Lamp manufacturers and Maine lamp distributors were consulted to select the type of lamps most commonly sold to industry. The most common four foot lamp identified was "cool white" both TCLP compliant and non-compliant T12 models; and "741" T8 models. For the three major lamp manufacturers, comparable models for T8 "741", and T12 cool white bulbs have been chosen. In order to account for variability in individual lamps produced during a production batch, and also variability among production batches, at least four production batches and up to five lamps within each batch will be analyzed. Since the leaching potential for mercury is dependent on the form of mercury present in a lamp [elemental mercury vs mercury oxides], spent lamps will also be tested to more accurately represent lamps being placed in the solid waste stream. The complete procedure is documented in Appendix B sampling SOP P1.

Worksheet 12b gives an accounting of the provided lamp models. The exact number of samples tested will depend on variability assessments after four new lamps and four used lamps from each lamp model are tested. Variability assessment is described on worksheet 30, Data Usability Assessment.

For total mercury, 5 new lamps from each of four production batches, as well as five used lamps will be provided for each lamp model number. For TCLP mercury, five new lamps representing four production batches, as well as five used lamps will be provided for each lamp model number. Variability will be assessed after an initial test batch of each lamp model has been analyzed, and additional samples will be analyzed to provide data to meet the project objectives.

The following EPA-NE QAPP Worksheets are included in Appendix A:
Worksheet 12b Sampling Locations, Sampling and Analysis Method/ SOP Table

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- 9. Sampling Procedures and Requirements
 - 9.1. Sampling SOPs: SOP P1 is included in Appendix B
 - 9.2. Sampling SOP modifications: Any modifications to SOP P1 must be documented and discussed with the project QA Manager. The QA Manager will be responsible for communicating any relevant information to the laboratory/ other case team members, and for including a discussion of SOP modifications in the Data Usability Report and Final Project Report.

The following EPA-NE QAPP Worksheet is included in Appendix A: Worksheet 13 Project Sampling SOP Reference Table

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- 10. Sample Handling, Tracking and Custody Requirements
 - 10.1. Sample Collection Documentation:
 - 10.1.1. Field Notes:
 - 10.1.1.1. A sample identification form [attached at end of section] will be used to document lamp identification numbers. This form will be completed by the sample coordinator, and sample labels will concurrently be affixed to each lamp. Each form will include: Project name, lamp distributor information, sample identification number, lamp manufacturer, lamp model number and lamp batch number.
 - 10.1.1.2. Shipping Records: Samples will be packed to minimize breakage and shipped via UPS carrier to Veritech Laboratories. A copy of the UPS packing slip will be retained by the sample coordinator.
 - 10.1.2. Field Documentation Management System: Sample identification forms and shipping records will be submitted to the QA Manager to be retained through completion of the project, and archived with all project records.
 - 10.2. Sample Handling and Tracking System: Sample identification numbers will be placed on the sample identification form, sample label, and sample chain of custody form. The sample identification form and a copy of the chain of custody forms will be retained by the project QA Manager. Samples with labels and chain of custody forms will be delivered to the analytical laboratory. Sample identification number will be used to track samples throughout the sampling/ analysis process. Worksheet 16 describes the sample handling flow. Sample labels will be placed directly on lamps using peal away labels that adhere to the surface of the lamp.
 - 10.3. Sample Custody
 - 10.3.1. Sampling/ Shipping: A sample chain of custody record [attached at end of section] will be completed prior to sample shipment. Sample identification numbers listed on each lamp will be recorded on the chain of custody record and will be cross-referenced to the sample identification form. The chain of custody record will be signed upon relinquishing the samples to the mail carrier, and shipped along with the samples to Veritech Laboratories. A copy of the chain of custody record will be retained by Project Sample Coordinator and submitted to the Project QA Manager.
 - 10.3.2. Laboratory Custody Records: Upon receipt, samples will be inspected and documented for acceptable condition. Samples are given unique lab sample numbers which are used to track associated laboratory records through the analytical/reporting process. Laboratory sample handling, tracking, and custody records are described in Section 3 [pages 10-20] of the Laboratory Quality Assurance Manual included in Appendix C.

The following EPA-NE QAPP Worksheets are included in Appendix A: Worksheet 16 Sample Handling Flow Diagram

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Sample Identification Form Fluorescent Lamp Study

Project:		Fluorescent Lamp Study			
Lamp Manu	facturer				
Sample ID	Production Batch	Production	n Batch Number	Model	Model Description
[Form for nev	v lamps]	<u> </u>		1	
Sample ID	Date Code		Manufacturer	Model	Model Description

[Form for used lamps]

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Sample Chain of Custody Record

ME DEP Fluorescent Lamp Study		PO Number:				
Deb Stahler, ME DEP	Standard turnaround time					
17 SHS				ta validation		
Augusta, ME 04333		Full deliverables for Tier III data validation Electronic Results				
(207) 287-7878		Send report to Deb Stahler				
Relinquished to Carrier						
	signature of MEDEP sample custodian date shipped			ate shipped		
D						
Received from Carrier	aiomatuma of Vani	tech sample custo	dian d	ate received		
	signature of veri	tech sample custo	ouran u	ate received		
Lab Sample Number	DEP Sample ID	Packing Box	Test Requested**	Sample Condition		
1	1	Number	1	[✓ if acceptable]		
		1	1	1		

^{**} Tests are for whole lamp analysis

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11. Field Analytical Method Requirements: NA

- 12. Fixed Laboratory Analytical Method Requirements:
 - 12.1. Laboratory Analytical Methods and SOPs: All SOPs have been included in Appendix D of this QAPP and are referenced on worksheet 20.
 - 12.2. Laboratory Analytical Method/ SOP Modifications: Any major modifications must be approved by the laboratory QA manager and the project QA manager, and must not impact the laboratory measurement performance criteria approved for this project. Two modifications to the laboratory procedure for TCLP leaching procedure have been incorporated in the SOP. These two modifications ensure that NEMA sample preparation standards in NEMA LL1 will be followed.
 - 12.3. Laboratory Instrument Calibration: All instruments must be calibrated according to the specifications of the analytical SOPs in Appendix D. This information is summarized on worksheet 21.
 - 12.4. Instrument/ Equipment Maintenance, Testing and Inspection Requirements:
 Preventive maintenance is outlined in Chapter 5 of the Laboratory Quality Assurance
 Manual [Veritech QAM]. A spare parts list is given for the mercury analyzer on page
 32 and a template for the Veritech preventive maintenance log is given on page 33.
 - 12.5. Laboratory Inspection and Acceptance Requirements for Supplies: Section 4.0 of the Veritech QAM addresses material procurement and control.

The following EPA-NE QAPP Worksheets are included in Appendix A:

Worksheet 20 Fixed Laboratory Analytical Method/ SOP Reference Table Worksheet 21 Fixed Laboratory Instrument Maintenance and Calibration Table

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13. Quality Control Requirements:

- 13.1. Sampling Quality Control: Sampling quality control consists of acquiring a representative sample of lamps for each model, and providing the laboratory with enough lamps to analyze a statistically valid number of samples. A Performance Evaluation sample will also be provided for both the TCLP mercury and total mercury tests. Worksheet 22a provides frequency and measurement performance criteria for field QC. All sampling will adhere to the sampling SOP [P1] found in Appendix C.
- 13.2. Analytical Quality Control: All quality control activities outlined in the laboratory SOPs in Appendix D will be performed. MDL studies for all methods have been completed and submitted to ME DEP. MDL studies indicate that laboratory methods are sensitive enough to meet project quantitation limits [see worksheet 9b]. Analytical calibration criteria are summarized on worksheet 21. Analytical quality control criteria are summarized on worksheet 24a.

The following EPA-NE QAPP Worksheets are included in Appendix A:

Worksheet 22a Field Sampling QC Table

Worksheet 24a Fixed Laboratory Analytical QC Sample Table

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- 14. Data Acquisition Requirements: NA
- 15. Documentation, Records and Data Management
 - 15.1. Project Documentation and Records: Worksheet 26 summarizes project records.
 - 15.2. Laboratory Data Package Deliverables: Data reporting is discussed in the Veritech QAM section 9. For this project, full [regulatory] deliverables will be required to validate data according to tier III procedures outlined in Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Full deliverables include:
 - Copies of all original shipping documents
 - Copies of all original receiving documents
 - Copies of all original laboratory records of sample transfer, preparation, and analysis
 - All other project specific documents in the possession of the laboratory
 - Sample data package documentation:
 - Narrative
 - Tabulated summary forms for field sample data, laboratory standards, QC samples, and blanks
 - Raw data for field samples, standards, QC sample, and blanks
 - Laboratory logbook pages for preparation and analysis
 - Chain of Custody records
 - 15.3. Data Reporting Formats: Data reporting is discussed in the Veritech QAM section 9.4 and 9.5. Examples of laboratory reports and verification checklists are provided in Appendix E.
 - 15.4. Data Handling and Management:

All data entry forms are signed and dated by the analyst and submitted with the routing sheet for incorporation into the project file. Analysts check 100% of their own work, signing and dating all data. The section supervisor checks 100% of all processed data to ensure: numerical calculations are correct; correct interpretation of instrument charts; dilutions are reported correctly; samples have been prepared and analyzed within holding times; QC samples meet criteria; results have been rounded and reported properly; and all errors have been crossed out with a single line, initialed and dated.

See Veritech QAM section 9.1 to 9.8.

All laboratory data will be validated according to tier III procedures outlined in Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Validation reports will be submitted to ME DEP for usability assessment.

15.5. Data Tracking and Control: Section 11 of the Veritech QAM describes laboratory records management and document control. All laboratory data and data validation reports will be submitted to the project QA manager at ME DEP. ME DEP will retain all project records and reports for at least five years.

The following EPA-NE QAPP Worksheet is included in Appendix A: Worksheet 26 Project Documentation and Records Table

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16. Assessments and Response Actions:

- Sampling Assessments:
 - Lamps from different manufacturers must be comparable within classifications. Prior
 to selection, Enid Mitnik and Deb Stahler will confer to assess characteristics such as
 nominal watts, expected lamp life, and color temperature. Manufacturer model
 numbers will be compared to specifications for all lamps of a given bulb type and
 TCLP rating. Corrective action includes revising the lamp model selected for study.
 - Lamps must be shipped to the laboratory and are subject to breakage. A 10% surplus stock will be shipped to minimize the need for reshipping due to breakage. When lamps arrive at the laboratory, MEDEP and Veritech will confer to assess whether sufficient samples have been received. Lamps will be re-shipped as necessary.
- Laboratory Assessment
 - A single blind Performance Evaluation sample will be shipped to Veritech
 Laboratories from Environmental Resource Associates. Veritech will analyze the PE
 sample and report results prior to analyzing samples. If results are not within ERA
 specified limits, any laboratory analytical problems must be corrected, and a PE
 analyzed within acceptance limits before analyzing samples.
 - Laboratory Audits: The most recent internal laboratory audit report and Army Corps of Engineers audit report have been forwarded to ME DEP for review, and are attached in Appendix F.
 - Each analyst must complete an annual demonstration of capability for each analytical test. A copy of analyst demonstration of capability is included in Appendix G.
 - After one analytical batch of each TCLP and total Hg testing has been completed, the laboratory metals supervisor will review data to assure QC criteria are being met. Any analytical problems must be corrected before continuing. Any QA concerns should be communicated to MEDEP. Samples used for the first four analytical batches will be identified by MEDEP and results from these analyses will be used to assess analytical variance and estimate the final number of samples needed to meet project goals.
 - The laboratory data package will be reviewed by the data validator to assure that a tier III data validation can be performed. If more laboratory data is needed for the validation process, the data validator will work with the laboratory QA office to acquire the needed data.

The following EPA-NE QAPP Worksheets are included in Appendix A: Worksheet 27b Project Assessment Table

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17. QA Management Reports: A list of QA management reports is included in worksheet 28. All QA management reports will be included in the final project report, and will be retained at ME DEP for five years.

The following EPA-NE QAPP Worksheet is included in Appendix A: Worksheet 28 QA Management Reports Table

- 18. Verification and Validation Requirements: All laboratory data will be validated according to tier III procedures outlined in Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses.
- 19. Verification and Validation Procedures: Before a report is issued, Veritech Laboratories will verify and validate all data according to procedure described in the Veritech QAM section nine. All laboratory data will be validated according to tier III procedures outlined in Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses.

The following EPA-NE QAPP Worksheet is included in Appendix A:

Worksheet 29b Data Validation Summary Table Worksheet 29c Data Validation Modifications

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20. Data Usability/ Reconciliation with Project Quality Objectives:

To assure data for TCLP pass/fail can be established, statistical methods from SW-846, chapter 9 will be used to assess the data usability/ number of samples required. See in particular formulas 2a, 4, and 8 from table 9-1. The TCLP limit of 0.2 mg/L for mercury will be used as the regulatory threshold in formula 8. Categories [manufacturer and bulb type] will be considered separately and together [within bulb type]. Bulb type is defined as all bulbs within a certain size [4' T8] and TCLP classification [P/F]. If the number of samples calculated is less than the number of samples analyzed, the data will be usable. If not enough validated data is generated, no conclusions can be made regarding TCLP. More samples may be analyzed to satisfy the sample number requirement.

Enviro-Calc® Public Domain Software will be used to assess total mercury results, to determine if enough sample results were obtained to estimate the mean $\pm 10\%$ at a confidence level of 95%. Equations used for this calculation are based on relative standard deviation [CV] of the validated results and are described below:

The equations for determining the number of samples to estimate a mean concentration when variability is estimated in relative terms using the coefficient of variation (relative standard deviation) are:

First Pass Equation - $n = [Z(1-alpha/2)*CV/d(r)]^2$

Second Pass Equation - $n = [t(1-alpha/2)*CV/d(r)]^2$

Where:

Z = the standard normal deviate from the Z distribution using alpha for a two-tailed distribution:

CV = relative standard deviation;

t = t score for stated confidence level [e.g. 95%]; and

d(r) = the amount of error tolerable in the estimate of the average in relative terms (e.g., 10%).

More samples may be analyzed to achieve the total mercury criteria set above. Alternatively, if the number of samples needed is impractical, the confidence interval will be calculated for the available data at 95% confidence.

The following EPA-NE QAPP Worksheet is included in Appendix A: Worksheet 30 Data Usability Assessment